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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/590,618	08/24/2006	Shifeng Pan	P1152US10	2237		
	7590 07/08/200 <b>ISTITUTE OF THE</b>	8	EXAMINER			
NOVARTIS RE	ESEARCH FOUNDAT	SHIAO, REI TSANG				
SAN DIEGO, C	AY HOPKINS DRIVE CA 92121-1127	, <b>5</b> U11E E223	ART UNIT	PAPER NUMBER		
			1626			
			NOTIFICATION DATE	DELIVERY MODE		
			07/08/2008	ELECTRONIC		

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPLegal@gnf.org jclarke@gnf.org

	Application No.	Applicant(s)				
	10/590,618	PAN ET AL.				
Office Action Summary	Examiner	Art Unit				
	REI-TSANG SHIAO	1626				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence ad	ldress			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	<b>J.</b> nely filed the mailing date of this c D (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on <u>24 Au</u>	igust 2006.					
	action is non-final.					
3) Since this application is in condition for allowar	nce except for formal matters, pro	secution as to the	e merits is			
closed in accordance with the practice under E						
Disposition of Claims						
4)⊠ Claim(s) <u>1-14</u> is/are pending in the application.						
	4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6)☐ Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) 1-14 are subject to restriction and/or e	election requirement.					
Application Papers						
9) The specification is objected to by the Examine	r					
10) The drawing(s) filed on is/are: a) acce		Examiner				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119	animon ricio uno allacinos cinico	7.00.017.01.101111.1	102.			
		(d) = = (f)				
12) Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a)	-(α) or (τ).				
a) All b) Some * c) None of:	have been received					
1. Certified copies of the priority documents		an Na				
	2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da 5) Notice of Informal P					
Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date	6) Other:					

### **DETAILED ACTION**

1. Claims 1-14 are pending in the application.

#### Election/Restriction

2. Restriction is required under 35 U.S.C. 121 and 372.

## Lack of Unity Requirement

- 3. This application contains the following inventions or groups of inventions, which are not so linked as to form a single inventive concept under PCT Rule 13.1.
- I. Claims 1-14, in part, drawn to compounds/compositions of formula (I), wherein the variable m is 2, the variable n is 1 thereof; the variable E is CR8 or N thereof; when the variable Y represent heteroaryl selected from the moiety defined in

variable X represent heteroaryl selected from the moiety defined in claim 4 thereof, i.e.,

Art Unit: 1626

thereof; R1-R5 independently do <u>not</u> represent heteroaryl or heterocycloalkyl thereof, the variables R1-R5 independently are not substituted with heteroaryl or heterocycloalkyl group thereof, and their methods of use. If this group is elected, applicants are requested to elect a single species for the search purpose.

II. Claims 1-14, in part, drawn to compounds/compositions of formula (I), containing compounds of formula (I) not embraced in Group I. If this group is elected, applicants are requested to elect a single species for the search purpose. This group is subject further restriction if it is elected.

It is noted that claim 13 is drawn to "use" claims. Claim 13 provides for the use of derivatives of phosphoric acid ester, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F.

Application/Control Number: 10/590,618

Art Unit: 1626

Supp. 131, 149 USPQ 475 (D.D.C. 1966). However, claim 13 herein is drawn to methods of use or processes of making for prosecution of restriction requirement.

Upon thorough consideration of the claims, the examiner has determined that a lack of unity of invention exists, as defined in Rule 13.

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1(a), indicates that the application should relate to only one invention, or if there is more than one invention, inclusion is permitted if they are so linked to form a single general inventive concept.

Annex B, Part 1(b), indicates that "special technical features" means those technical features which as a whole define a contribution over the prior art.

Annex B, Part 1(c), further defines independent and dependent claims. Unity of invention only is concerned in relation to independent claims. Dependent claims are defined as a claim which contains all the features of another claim and is in the same category as the other claim. The category of a claim refers to the classification of claims according to subject matter, e.g. product, process, use, apparatus, means, etc.

Annex B, Part 1(f) indicates the "Markush practice" of alternatives in a single claim. Part 1(f(i)) indicates the technical interrelationship and the same or

Page 5

corresponding special technical feature is considered to be met when: (A) all alternatives have a common property or activity, and (B) a common structure is present or all alternatives belong to a recognized class of chemical compounds. Further defining (B) in Annex B, Part 1(f)(i-iii), the common structure must; a) occupy a large portion of their structure, or b) the common structure constitutes a structurally distinctive portion, or c) where the structures are equivalent and therefore a recognized class of chemical compounds, each member could be substituted for one another with the same intended result. That is, with a common or equivalent structure, there is an expectation from knowledge in the art that all members will behave in the same way. Thus, the technical relationship and the corresponding special technical feature result from a common (or equivalent) structure which is responsible for the common activity (or property). Part 1(f(iv)) indicates that when all alternatives of a Markush grouping can be differently classified, it shall not, taken alone, be considered justification for finding a lack of unity. Part 1(f(v)) indicates that when dealing with alternatives, it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered, but does not imply that an objection shall be raised.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Again, this list is not exhaustive, as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention by identifying another specific embodiment not listed in the exemplary groups of the invention and examiner will endeavor to group the same.

Art Unit: 1626

The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art, see Austel et al. CAS: 119:117098. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unit of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter impose a burden on any examination of the claimed subject matter.

**4.** Applicants are advised that the reply to this requirement to be complete must include an election of invention to be examined even though the requirement be traversed (37 CFR 1.143).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph

Art Unit: 1626

K. McKane can be reached on (571) 272-0699. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from

the Patent Application Information Retrieval (PAIR) system. Status information

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For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

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USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/REI-TSANG SHIAO /

Rei-tsang Shiao, Ph.D. Primary Patent Examiner Art Unit 1626

June 30, 2008